AUG - 3 2001

K010295/A

510 (k) Summary

1. Submitters Identification:

MicroStim Technology Incorporated
7881 NW 90th Ave
Tamarac, FL 33321
(954) 720-4383

Medical Device Establishment Registration Number: 2939358
PD: 84 GZJ Stimulator Transcutaneous Nerve Stimulator (Pain Relief)
CN: TENS
TN: MicroStim 100i

NAME OF THE DEVICE: MicroStim 100i

Predicate information: This device is a transcutaneous electrical nerve stimulator and we submit that it is substantially equivalent to our device, the IndicaTens 5XS, which carries the 510(k) number K900668B.

Device description:

The device is used to transmit very small electrical pulses through the skin to block the transmission of pain impulses to the brain.

Intended use:

Transcutaneous Electrical Nerve Stimulation (TENS) devices are used for the symptomatic relief of chronic (long term) intractable pain and as an adjunctive treatment in the management of postsurgical traumatic pain problems.

Discussion of clinical tests performed on the device:

None

Discussion of non-clinical tests performed on the device

Device has been bench tested to guarantee that the outputs, (frequencies, waveforms, and timers) all perform to specifications.

Conclusions:

The MicroStim 100i puts out the identical waveforms, frequencies, and currents, as the IndicaTens 5XS (510(k) number K900668B) and differs only in that this device is a table top unit with a computerized control of the frequency selection and timers.

It has the same intended use as the predicate device and technological testing raises no new questions about safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Joel Rossen, DVM
Chief Executive Officer
Microstim Technology, Inc.
7881 NW 90th Avenue
Tamarac, Florida 33321

Re: K010295
Trade/Device Name: MicroStim 100i
Regulation Number: 882.5890
Regulatory Class: II
Product Code: GZJ
Dated: Undated
Received: May 11, 2001

Dear Dr. Rossen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) # K010295

Device Name: MicroStim 100i

Indications for use:

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Concurrence of CDRH, Office of device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription use ___
Per 21CFR 801-109

Over the Counter-Use
(Optional format 1-2-96)

510(k) Number K010295